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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/621,574 07/21/00

023280

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NEW YORK, NY 10018

EXAMINER

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/02/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**NOTICE OF ALLOWABILITY**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

- ☒ This communication is responsive to 4-9-01
- ☒ The allowed claim(s) is/are 3, 1-69
- ☒ The drawings filed on 7-21-2000 are acceptable.
- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☒ received in Application No. (Series Code/Serial Number) 07/844,664
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☐ Applicant MUST submit NEW FORMAL DRAWINGS
- ☐ because the originally filed drawings were declared by applicant to be informal.
- ☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_
- ☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.
- ☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

- ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Interview Summary, PTO-413
- ☐ Examiner's Amendment/Comment
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Examiner's Statement of Reasons for Allowance

*S. Kishore*  
S. Kishore, PhD

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### DETAILED ACTION

The preliminary amendment filed on 7-21-00 is acknowledged.

#### *Specification*

1. The disclosure is objected to because of the following informalities: the specification does not contain a brief description of the drawings.

Appropriate correction is required.

#### *Claim Rejections - 35 U.S.C. § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the percentages on weight basis and the dependent claim 34 recites mole percents. This is confusing.

What is being conveyed by “wherein the concentration of surfactant is between 20-50 mol-% of the concentration of said surfactant causes-----” in claims 34 and 50. This

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statement is confusing. Furthermore, according to this claim the surfactant solubilizes the lipid and therefore, one would expect a solution and not transfersomes.

What is being conveyed through “permeation capacity ----- mechanical fragmentation” as recited in claim 49? How can fragmentation determine the permeation capacity?

What is being conveyed by ‘phosphate salts thereof and sulfate salts thereof’ as recited in claim 67? Some of the compounds recited are salts of acids. For example deoxycholate, myristate, oleate etc., are anionic in nature having a metal cation. How can one form a further salt?

*Claim Rejections - 35 U.S.C. § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 31-42, 46-50, 52-60, and 63-69 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0220 797.

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EP discloses liposomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation (note the abstract, column 1, examples and claims). Instant claims which are so vague do not distinguish over the prior art.

6. Claim 31, 32, 34-42, 46-47, 62-86 and 101-155 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer (BBA, 1986).

Mayer teaches liposomes containing an amphiphilic lipid and inulin and a method of preparation (note the abstract and Materials & Methods section).

*Claim Rejections - 35 U.S.C. § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 31-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797.

As pointed out above, EP discloses liposomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation (note the abstract, column 1, examples and claims). It is unclear whether EP teaches all the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulatable by an artisan to obtain the best possible results.

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EP does not teach all the claimed active agents. It is deemed however, to be obvious to an artisan to encapsulate any active agent since the novelty of the preparation rests on the liposomes and not the active agent which is encapsulated.

9. Claims 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797, further in view of Mayer cited above.

EP does not teach subjecting liposomes to an extrusion procedure.

Mayer teaches that one can obtain a homogeneous population of liposomes by subjecting them to extrusion through filters (note the abstract). It would have been obvious to one of ordinary skill in the art to subject the liposomes of EP to extrusion since such a process produces a homogeneous population of liposomes.

10. Claims 51 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797 and Mayer cited above, individually or in combination further in view of Patel (FEBS Letters).

Neither EP nor Mayer teach the active agent encapsulated to be insulin.

Encapsulation of active agents such as insulin not taught by EP or Mayer would have been obvious to one of ordinary skill in the art since Patel shows the routine use of liposomes for the encapsulation of insulin and an artisan would expect at least similar results (note the entire article).

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11. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797 and Meyer cited above, individually or in combination further in view of Wallach (4,911,928).

EP and Meyer do not teach the encapsulation of pheromones, insulin, pesticides and herbicides.

Wallach while disclosing vesicles containing edge active substances such as those in the instant invention, teaches that active agents such as pheromones, insulin and pesticides can be encapsulated in the vesicles. Encapsulation of claimed active agents which are not taught by EP or Mayer, would have been obvious to one of ordinary skill in the art since Wallach shows the routine use of liposomes for the encapsulation of these agents and an artisan would expect at least similar results (note the abstract and col. 6, lines 29-43).

The references cited above, are the same as in the parent application and hence no copies have been provided.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**December 4, 2000**

09/621574

Attachment 3

**The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.**

**Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.**